REMARKS/ARGUMENTS

Claims 1-12 and 24 are currently pending. Claims 1, 2, 3 and 5 have been amended. Claim 23 has been cancelled. Applicants submit that the amendments place the application in condition for allowance or in better form for appeal and request that the amendment be entered. Review and reconsideration on the merits are requested in view of the following comments.

The Office has maintained the position that claim 23 is directed to an independent or distinct invention. Accordingly, claim 23 has been cancelled in an effort to expedite allowance of the case. Claim 5 has been amended to correct a typographical error in the previous amendment.

Claims 1, 2, 6-9 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,839,177 (the '177 patent). Claim 1 has been amended to indicate that the skeletal muscle relaxant is selected from the group consisting of cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof. The '177 patent fails to disclose or suggest the use of the specified muscle relaxants. Furthermore, applicants maintain the position that the claims are patentably distinguishable over the '177 disclosure since claim 1 is clearly directed to a population of extended release beads that are neither disclosed nor suggested in the '177 patent. Although the Office has not given the limitation "multi-particulate" any patentable weight since it is in the preamble of the claim, applicants respectfully submit that the body of the claim clearly is directed to a multi-particulate dosage form since the body of the claim recites a population of extended release beads. Applicants respectfully submit that claim 1 and the claims dependent thereon are patentable over the cited reference and request that the rejection be withdrawn.

Claims 1-11 and 24 stand objected to as being non-enabling for the generic class of muscle relaxants. As indicated above, claim 1 has been amended to limit the skeletal muscle relaxant to cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof. Applicants submit that the specification is enabling with respect to the currently claimed subject matter. Therefore, applicants respectfully request that the rejection be withdrawn.

Claims 1-11 and 24 stand objected to because of the limitation "immediate release" has been removed from the instant claim 1. The Office indicates that this is in error. However, applicants submit that the elimination of the term "immediate release" from claim 1 has no impact on the scope of claim 1 as originally presented. The recitation of "immediate release" beads in claim 1 as originally presented simply referred to another name for the active-containing core particle that is coated to form the extended release beads. Claim 1 as originally presented and as amended recites a population of extended release beads wherein the extended release beads comprise an active-containing core particle that is coated with an extended release coating. Once the active-containing core particles are coated with the extended release coating, they are no longer immediate release beads. This term is simply used to identify the precursors used in forming the extended release beads. Claim 1 as originally filed did not require a separate immediate release bead population. Claims to a pharmaceutical dosage form containing both an immediate release bead population and extended release bead populations are covered in claim 5 of the pending application. Therefore, applicants respectfully request that the objection be withdrawn.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance and favorable action on the merits is requested. Any questions concerning this application may be directed to applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,

John F. Kane, Reg. No. 44,815

THOMPSON HINE LLP
2000 Courthouse Plaza NE
10 West Second Street
Dayton, Ohio 45402-1758
(937) 443-6816

456028-v1